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10/563,956	01/10/2006	Bernd Karl Friedrich Kremer	18724.009	3600

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EXAMINER	
JUEDES, AMY E	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,956	KREMER ET AL.	
	Examiner	Art Unit	
	AMY E. JUEDES	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *54 and 73-99* is/are pending in the application.

4a) Of the above claim(s) *75-77 and 82-87* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *54,73,74,78-81 and 88-99* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 9/9/08, is acknowledged.

Claims 54, 77-79, and 99 have been amended.
Claims 54 and 73-99 are pending.

2. Applicant's election without traverse of a CD3/CD14 expressing cell as the species of tolerance inducing cell, and autoimmune disease as the species of disease associated with disturbed self tolerance, in the reply filed on 9/9/08, is acknowledged.

Claims 75-77 and 82-87 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected species.

Claims 54, 73-74, 78-81, and 88-99 read on the elected invention and are being acted upon.

3. Acknowledgment is made of applicant's claim for priority. The instant specification on page 1 indicates that the instant application is a continuation of International Application PCT/EP2004/00109. However, the instant application is the national stage entry of said international application. The specification should be amended to indicate that the instant application is the national stage entry of PCT/EP2004/00109, and not a continuation of PCT/EP2004/00109. Furthermore, the specification indicates that the instant application claims benefit of U.S. Application 10/520,931. However, the specification should indicate how the instant application relates to application 10/520,931 (i.e. CON, DIV, CIP). Correction is required.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 93-96 and 98 are rejected under 35 U.S.C. 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) A method of preventing, treating, or preventing and treating a disease associated with disturbed self-tolerance comprising administering a composition comprising a tolerance inducing CD3/CD14 expressing cell, wherein said composition further comprises "a regulatory T lymphocyte that expresses a CD4 antigen and a CD25 antigen", wherein said composition comprises a multitude of tolerance inducing cells "equal in number to a multitude of said regulatory T lymphocytes", and wherein said multitude of said regulatory T lymphocytes are in a quantity of "at least 1 x 10^5 cells/ml" (Claims 93-95).

B) A method comprising administering a composition comprising lymphocytes, wherein lymphocytes comprise "at least 10% of the total population of cells" (Claims 98).

C) A method wherein the M-CSF concentration is "1 to 20 ug/ml" (Claim 96).

Applicant indicates that support for the new claims can be found on pages 13-14, 17-19, 22-24, 26, and 29-32 of the specification.

A review of the specification fails to reveal support for the new limitations.

Regarding A), the specification on page 20 discloses that the tolerance inducing cell of the invention can be part a cell population comprising lymphocytes. This provides support for a method of administering a tolerance inducing cell composition comprising lymphocytes, but not for the method of claim 93 which recites that the cell preparation comprises "regulatory T lymphocytes expressing CD4 antigen and a CD25 antigen". The specification on pages 31-32 further discloses the tolerance inducing cells of the invention can be used in vitro to expand regulatory T lymphocytes by co-culturing equal numbers of transplant inducing cells and lymphocytes (including a quantity of at least 1 x 10^5 cell/ml of said lymphocytes). The specification discloses that the co-culture results in the expansion of CD4+CD25+ T lymphocytes, and that said lymphocytes can be administered to a subject. However, the disclosure by the specification of culturing tolerance inducing cells in vitro with lymphocytes to expand CD4+CD25+ regulatory T cells for administration to a subject has a narrower scope than the instant claims. For example, the claims might encompass administering CD4+CD25+ regulatory T cells purified directly from a subject along with a tolerance inducing cell. In contrast, the specification only discloses co-culturing a tolerance inducing cell with a lymphocyte to generate said administered regulatory T cells. Additionally, the specification does not disclose administering a cell preparation comprising an equal number of

regulatory T cells and tolerance inducing cells, or administering 1 x 10^5 regulatory T cells per ml, as recited in claims 94-95. Rather the specification discloses culturing tolerance inducing cells with an equal number of lymphocytes in vitro (including 1 x 10^5 lymphocytes/ml).

Regarding B), at page 20, the specification discloses that cell preparations comprising tolerance inducing cells can comprise about 10-50% of lymphocytes. However, this has a different scope than the instant claims which recite that "at least 10%" of the cells in composition are lymphocytes. The recitation of "at least 10%" has no upper limit, and has a different scope than the range of 10-50% disclosed by the specification. For example, the claims might encompass administering a composition comprising 90% lymphocytes, while the specification only discloses populations comprising 10-50% of, lymphocytes.

Regarding C), the specification on page 23 discloses culturing monocytes with 2 to 20 ug/l of M-CSF. Additionally, original claim 6 recited a concentration of 1 to 20 ug/l of M-CSF. However, the instant claims recite that the concentration of M-CSF is "1 to 20 ug/ml", which corresponds to 1000 to 20,000 ug/l. This concentration range is much higher than the concentrations disclosed by the specification and claims as filed.

6. Claim 81 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that "GM-7" hybridoma cell line of DSM Accession No. ACC2542 is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the pertinent cell lines. See 37 CFR 1.801-1.809. In addition to the conditions under the Budapest Treaty, Applicant is required to assure that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications (see 37 CFR 1.808 (a)(2) and MPEP 2410-2410.01).

The specification on page 13 indicates that the hybridoma cell line producing the GM-7 antibody was deposited according to the rules of the Budapest convention at DSMZ (Deutshche Sammlung

von Mikroorganismen and Zellkultur GmbH, Branuschweig, Germany) under accession no. DSM ACC2542. However, 37 CFR 1.809 requires that the specification shall contain the date of the deposit and the address of the depository. Additionally, no assurance regarding the restrictions to the availability of the deposit, as indicated above, have been provided.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, Applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the original deposit is made after the effective filing date of an application for patent, the applicant should promptly submit a verified statement from a person in a position to corroborate the fact, and should state, that the biological material which is deposited is a biological material specifically identified in the application as filed, except if the person is an attorney or agent registered to practice before the Office, in which the case the statement need not be verified. See MPEP 1.804(b).

7. Claims 54, 73-74, 78-81, and 88-99 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

a method of treating autoimmune disease comprising administering a CD3+CD14+ cell, wherein the cell is obtained by a process comprising isolating a blood cell population comprising monocytes and lymphocytes, multiplying said cell population with M-CSF, followed by cultivating said cell population with γ-IFN, and a method for treating autoimmune disease comprising administering a cell obtained by a process comprising isolating a blood cell population comprising monocytes and lymphocytes, multiplying said cell population with M-CSF, followed by cultivating said cell population with γ-IFN,

does not reasonably provide enablement for:

a method of preventing, treating, or preventing and treating a disease associated with disturbed self tolerance comprising administering a tolerance induce cell expressing a CD3 antigen and a CD14 antigen, a method wherein said CD3 and CD14 expressing tolerance inducing cell is obtained by multiplying a monocyte with M-CSF/γ-IFN, or by cultivating cells simultaneously with M-CSF and γ-IFN, a method of preventing, treating, or preventing and treating a disease associated with disturbed self tolerance comprising administering a tolerance inducing cell obtained by isolating monocytes and multiplying said monocytes with M-CSF simultaneously or following said M-CSF culture with a medium containing γ-IFN.

The specification disclosure is insufficient to enable one skilled in the art to practice the invention as claimed without an undue amount of experimentation. Undue experimentation must be considered in light of factors including: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill in the art, the level of predictability of the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention, in re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

"The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art." In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling (MPEP 2164.03)" The MPEP further states that physiological activity can be considered inherently unpredictable.

The instant claims are drawn to a method of preventing or treating a disease associated with disturbed self-tolerance comprising administering a self-tolerance inducing cell expressing CD3/CD14 and/or made by culture in M-CSF and γ-IFN. The specification does not define diseases associated with disturbed self-tolerance, but discloses that said diseases include allergy and autoimmune disease. Since allergy is an aberrant immune response to a foreign antigen (and not a self antigen), it must be assumed that the diseases encompassed by the claims might reasonably encompass any type of disease involving a "disturbed" immune response. For example, the claims might encompass treating viral infections such as HIV that result in immune suppression. The claims might also encompass treating cancer, which can be result from a failure of the immune system to recognize cancerous self tissues (i.e. a disease of "disturbed" self tolerance). Thus, the claims encompass treating a wide range of diseases of different etiologies and pathological mechanisms. For example, the goal of treating cancer or viral infection is to boost the immune response, while treating autoimmune disease involves suppression of an immune response. It is unlikely that a single treatment would be effective for the broad range of diseases encompassed by the instant claims. Additionally, the instant claims encompass not only treatment,

but prevention of disease. Given its broadest reasonable interpretation, “prevention” encompasses treating a subject such that not signs or symptoms of disease ever develop. However, the "prevention" of diseases such as autoimmune disease is highly unpredictable. For example, even diagnosing autoimmune disease is very difficult, and while some treatments are available a "cure” that prevents autoimmune disease has yet to be discovered (see Progress in Autoimmune Disease Research, 2005, page 7 in particular). Thus, given the difficulty in even diagnosing autoimmune disease, it would be highly unpredictable as to whether a therapy could be given to a healthy individual in order to prevent any signs or symptoms of disease from ever occurring, as is encompassed by the instant claims.

Additionally, claims 54 and 73-74, 78-81, and 88-99 are drawn to a method of prevention/treatment comprising administering a cell that expresses CD3 and CD14. CD14 is a marker for monocytes, while CD3 is part of the TCR complex expressed exclusively by T cells. Furthermore, dependent claims 78-79 specify that the cells are made by culturing monocytes. Thus, it appears that the cells of the instant claims are CD3 expressing monocytes. It is noted that the recitation of a CD3 expressing cell encompass cells in which CD3 transcripts are translated endogenously and transported to the cell surface. CD3 is expressed at the cell surface as part of a complex with the TCR. However, CD3 is not expressed at the cell surface in the absence of the TCR (see Berkhout et al., page 8529 in particular). Furthermore, the expression of the TCR receptor is an extremely complex process that it tightly developmentally regulated, and requires rearrangement of the germ line TCR genes (see Janeway and Travers, pages 6:9-6:11, in particular). Thus, is extremely unlikely that a non-T cell would express an endogenously derived TCR at the cell surface, a requirement for cell-surface expression of endogenously derived CD3 polypeptides. However, it is known that antigen presenting cells can acquire CD3/TCR complexes via transfer from T cells during co-culture (see Busch et al., 2008). The transfer of CD3 from T cells results in the detection of CD3+ APCs by FACS analysis. Thus, it appears likely that the CD3 “expressing” monocytes described by the instant specification are in fact CD3+ monocytes that have acquired CD3/TCR complexes by co-culture with T cells. In fact, the instant specification demonstrates in Example 4 that the expression of CD3 by the monocytic transplantation acceptance inducing cells requires the presence of lymphocytes (i.e. T cells) during the cytokine culture. This further supports the notion that the CD3 “expression” by the monocytic tolerance inducing cells is actually acquired by transfer from T cells present in the co-culture. Thus, given the ability of APCs to acquire CD3 from T cells during co-culture, it is likely that the

acquisition of CD3 depends on the presence of lymphocytes in the co-culture, but not on the particular cytokine combination used to stimulate the cells. Thus, CD3+CD14+ cells might be generated using other cytokine combinations by co-culture with lymphocytes.

Additionally, the generation of monocytes capable of suppressing an immune response is unpredictable and highly dependent on the cell culture conditions employed. For example, culture with certain cytokines results in the ability of macrophages or monocytes to support antigen-specific T cell responses, while other cytokines induce macrophages/monocytes that suppress T cells (see Mahnke et al., 2007, page 8). Furthermore, the phenotype and function of macrophages/monocytes is also affected by interaction with other cell types, including T cells (See Mahnke et al., 2007, page 8). In fact, even the effect of γ-IFN in combination with M-CSF (as recited in the instant claims) on monocytic cells is highly unpredictable depending on the timing of cytokine culture. For example, monocytic cells cultured with M-CSF can suppress T cells in vitro, but that effect is abrogated if γ -IFN is added simultaneously with the M-CSF during the culture (see Munn et al., 1996, of record, page 530 in particular). However, γ -IFN does not abrogate the suppressive effect of the monocytic cells if it is added after the M-CSF cultures have already been established (see page 530 in particular). Thus, the generation of cells capable of inducing tolerance is unpredictable, and is highly dependent on the particular culture conditions used. Furthermore, given the fact that monocytic cells might acquire CD3 from T-cells during co-culture, it is highly unpredictable whether any CD3+CD14+ cells (i.e. even those made by methods not involving culture with M-CSF and γ -IFN) would function to induce tolerance.

Furthermore, the instant claims encompass administering a CD3+CD14+ cell that has been made by a process comprising cultivating an isolated monocyte with M-CSF and IFNgamma. This encompasses culturing a purified population of monocytes to obtain a CD3+CD14+ cell. However, as noted above, example 4 of the specification demonstrates that the CD3+ cells are only obtained when monocytes and lymphocytes are co-cultured, and CD3+ cells are minimal when a more pure population of monocytes is used. Thus, based on the teachings of the specification, obtaining a CD3+CD14+ cell by culturing a pure population of monocytes with GM-CSF and γ -IFN would be extremely unpredictable.

Thus, given the unpredictability of the art and breadth of the claims, the instant specification must provide a sufficient and enabling disclosure commensurate in scope with the instant

claims. The instant specification demonstrates that peripheral blood mononuclear cells comprising monocytes and lymphocytes cultured with M-CSF, followed by γ -IFN, are able to reduce the severity of an animal module of autoimmune colitis. The instant specification further demonstrates that a proportion of the MCS/γ-IFN cultured cells are CD3+CD14+ as determined by FACS analysis. The specification does not demonstrate that these cells are responsible for suppressing colitis in vivo, nor does the specification provide evidence that any CD3+CD14+ cell (for example, those derived by transfer of CD3 onto monocytes in a co-culture with T cells in the absence of M-CSF/γ-IFN) are capable of treating autoimmune disease. Furthermore, an example of treating a single autoimmune disease is not commensurate in scope with the instant claims, which encompass prevention or treatment of any disease associated with disturbed self-tolerance. Additionally, the instant specification does not provide any examples that demonstrate that tolerance inducing cells can be produced as broadly claimed, including by culturing isolated monocytes (i.e. in the absence of lymphocytes) with M-CSF and g-IFN simultaneously. Furthermore, given the state of the art in which the expression of endogenous CD3 by non-T cells is highly unpredictable, the demonstration of a CD3+ monocyte by FACS analysis is not commensurate is scope with the instant claims which encompass any "CD3 expressing cell". Thus, the teachings of the specification are not commensurate in scope with the instant claims, which encompass preventing or treating any disease associated with disturbed self-tolerance with any CD14 and CD3 expressing cell, or with a cell made by culturing an isolated monocyte with M-CSF and γ-IFN simultaneously.

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or

provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 54, 73-74, 78-81, and 88-99 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 51-52, 74-77, and 84-105 of copending Application No. 10/520,931.

The '931 application claims a method suppressing transplant rejection reactions (i.e. a disease associated with "disturbed self-tolerance") comprising administering a cell of monocytic origin that expresses CD3 and CD14. Additionally, said method would inherently result in the "prevention" of autoimmune disease, since it is the same as the method of the instant claims. Furthermore, the '931 application claims that the monocytic cell can be made by culturing a monocyte with M-CSF and γ-IFN, that the cells are of human origin, that the cells express GM-7 antigen, and that the administered cell population comprises a lymphocyte, including a CD4+CD25+ regulatory T cell. The '931 application also claims administering the cells at the same concentrations and in the same solutions of the instant claims. Additionally, the '931 application claims the same concentrations of M-CSF and IFN-gamma for making the cells as that of the instant claims. As taught by WO 03/056830, monocyte derived cells that are capable of inducing tolerance are applicable for the treatment of diseases including autoimmune disease or transplantation rejection (see page 4 and 8 in particular).

This is a provisional obviousness-type double patenting rejection.

10. No claim is allowed. Claims 54, 73-74, 78-81, and 88-99 are free of the prior art.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, Ph.D. whose telephone number is 571-272-4471. The examiner can normally be reached on 6am - 2pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571-272-0878. The fax phone number for the

organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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